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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/735,863 | 12/15/2003 | Lee R. Brettman | 079259-0237 | 5328 |
| 23630 7590 12/24/2008 MCDERMOTT WILL & EMERY LLP 28 STATE STREET BOSTON, MA 02109-1775 | | | EXAMINER SCHWADRON, RONALD B | |
| | | | ART UNIT 1644 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/735,863

Applicant(s)

BRETTMAN ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-13, 18,22,26,31,36,40,41,46,51 and 55-98 is/are pending in the application.
- 4a) Of the above claim(s) 61,65-72,84-92 and 98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,8-13, 18,22,26,31,36,40,41,46,51,55-60,62-64,73-83 and 93-97 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

1. Applicant's election of the method of the newly added species 4 mg/kg in the reply filed on 10/14/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 70-72,84-89,92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/14/08. Claim 98 depends from a previously withdrawn claim and is withdrawn from consideration

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1,13,18,22,26,31,36,40,41,46,51,55-60,62,73-79 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1,8-13,18,22,26,31,36,40,41,46,51,55-60,62-64,73-83,93-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponath et al. (WO 98/06248) in view of Gordon et al. or Gordon et al. Applicants arguments have been considered and deemed not persuasive.

Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims (see claim 45, pages 6,28-30, Figures 11 and 12). Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). Ponath et al. disclose the antibody can be administered in multiple doses (see page 29, second paragraph). Ponath et al. teach that said patient can additionally received steroids or sulfasalazine (see page 30) or other immunosuppressive agents wherein 6-mercaptopurine is an art known immunosuppressive agent. Ponath et al. do not disclose the particular claimed administration protocols. The Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin (see entire reference) wherein said dosage is a starting point for future clinical studies. Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). A routineer would have started with the 3 mg/kg dosage disclosed by Gordon et al. and arrived at the claimed protocols using routine experimentation. The functional characteristics of claims 22/26/40/41 would have been achieved with the starting dosage of 3 mg/kg (see claims 31/46). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody wherein said antibody has the amino acid sequence recited in the claims and that the dosage and

schedule of administration used would be determined using routine experimentation whilst the Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin wherein said dosage is a starting point for future clinical studies and a routineer would have started with the 3 mg/kg dosage disclosed by Gordon et al. and arrived at the claimed protocols using routine experimentation. One of ordinary skill in the art would have been motivated to do the aforementioned because Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation whilst Gordon et al. references disclose that patients with inflammatory bowel disease or ulcerative colitis can be treated with a dose of 3 mg of humanized antibody against an alpha4 integrin wherein said dosage is a starting point for future clinical studies. Furthermore, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m. 2007 WL 1237837, at "13 (2007)" it was stated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill".

Regarding applicants comments about unexpected results, the claims under consideration recite multiple administrations of the antibody recited in the claims. The cited passages of the specification refers to a single administration of the antibody recited in the claim. Thus, said study is not germane to the claimed invention because it does not use the claimed method. Regarding applicants comments about Gordon et al., whilst the reference does not disclose use of the same antibody, it is merely cited as providing a starting point for antibody dosages to be used for the invention disclosed by Ponath et al. wherein both references relate to treatment of inflammatory bowel disease/ulcerative colitis using anti integrin antibodies. Ponath et al. disclose treatment of ulcerative colitis with humanized LDP-02 antibody. Ponath et al. disclose that the dosage and schedule of administration used would be determined using routine experimentation (see page 29, second paragraph). The MPEP section 2144.05 states:

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Primary Examiner, Art Unit 1644